510(k) Summary for the Restoration™ Modular System
(Device Modification for the 2 Piece Modular Revision Stem System)

SEP 23 2002

Proprietary Name:	Restoration™ Modular System
Common Name:	Femoral Hip Prosthesis
Classification Name and Reference:	21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Proposed Regulatory Class:	II
Device Product Code:	OR(87) LZO
For Information contact:	Jennifer A. Daudelin Regulatory Affairs Specialist Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677 (201) 831-5379 Fax: (201) 831-6038
Date Summary Prepared:	July 31, 2002

Device Description

The 2 Piece Modular Hip Stem, hereby referred to as the Restoration™ Modular System, is a modular system comprised of a proximal body, distal stem, and locking bolt. These three individual components utilizing a modular junction are assembled by the surgeon in the operating room or in situ to allow independent sizing of the proximal body and distal stem. This system is designed so that all proximal components will be able to mate with all distal components, thus affording optimal flexibility.

The Restoration™ Modular System components will be fabricated from Titanium (Ti6Al-4V) Alloy. The Cone and Broached body components as well as the Porous Stems will be offered with plasma spray or plasma spray and hydroxylapatite coatings.

Intended Use

This system is intended to be used for primary or revision total hip arthroplasty, as well as in the presence of severe proximal bone loss. The stems are intended to be used with Howmedica Osteonics femoral heads, unipolar and bipolar components, and acetabular components. These femoral stems are designed to be press fit into the proximal femur.

Substantial Equivalence

The substantial equivalence of the Restoration™ Modular System is based upon equivalence in intended use, materials, and design to the following Howmedica Osteonics device: Restoration™ Modular (2 Piece Modular System) (K013106).

Performance Data

A series of fatigue tests were performed to ensure the integrity of the Restoration™ Modular System. Testing was performed to evaluate the strength of the neck, proximal body, and distal stem regions of the system. 'Most severe case' components/assemblies were tested based upon the previous FEA results. Test methods were consistent with methods described in ISO 7206-4 and ISO 7206-6. The comparison of test results with defined performance criteria indicate that all tested components meet or exceed their defined performance values. In summary, the testing demonstrates that, in terms of mechanical properties, the modified Restoration™ Modular Components are substantially equivalent to the legally marketed predicate components in terms of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 2002

Ms. Jennifer A. Daudelin
Regulatory Affairs Specialist
Howmedica Osteonics Corp.
59 Route 17
Allendale, New Jersey 07401-1677

Re: K022549
Trade Name: Restoration™ Modular System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or Porous uncemented prosthesis
Regulatory Class:II
Product Code: LZO
Dated: July 31, 2002
Received: August 1, 2002

Dear Ms. Daudelin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

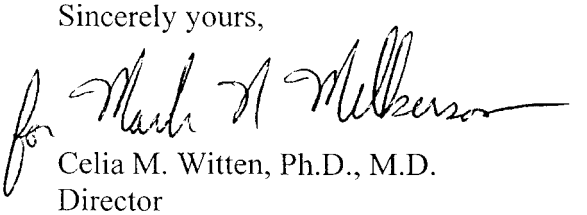
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K022549

Indications for Use

510(k) Number (if known):

Device Name:

Indications for Use:

The Restoration™ Modular System is intended to be used for primary or revision total hip arthroplasty, as well as in the presence of severe proximal bone loss. The stems are intended to be used with Howmedica Osteonics femoral heads, unipolar and bipolar components, and acetabular components. These femoral stems are designed to be press fit into the proximal femur.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milleson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K022549